

Remarks

Review and reconsideration of the First Office Action of February 18, 2005, is respectfully requested in view of the above amendments and the following remarks.

Claims 1, 3, 5, 9, 10, and 12 have been amended to more particularly point out and distinctly claim the subject matter of Applicant's invention. Amendment to Claims 1, 3, 5, 9, 10, and 12 are supported by the specification. Further, new claims 24 and 25 have been introduced. Claims 1-25 are now in the application. Applicant submits that the independent claims remaining in the application read on all species disclosed, and thus are generic.

Applicant has introduced new claims 24 and 25. Claim 24 is dependent from claim 1. Claim 25 is dependent from claim 24. Each of the new claims 24 and 25 is dependent, either directly or indirectly from amended claim 1. Full support for the subject matter of claims 24 and 25 can be found on page 9 of the application where it is stated:

The process and apparatus in accordance with the invention provides a simple and effective solution to this problem by equalizing, prior to the actual sterilization process, the temperature of all materials exposed to the atmosphere in the sterilization chamber. This is preferably achieved through repeated evacuation of the chamber and intermediate flushing with ambient air or oxygen at ambient temperature.

Thus, Applicant submits that no matter was introduced and that no new search is required for the subject matter claimed in the new claims 24 and 25.

Office Action

Turning now to the Office Action in greater detail.

Paragraphs 1 and 2

The Examiner objected to claim 1 for lack of clarity of the phrase " to a sterilization pressure lowering" . Applicant has amended claim 1 to include the requested connecting phrase showing that the sterilization pressure results in lowering the boiling point of water.

The Examiner objected to claim 3 for lack of clarity of the phrase "when operated at". The word "when" has been deleted as requested by the Examiner.

In response, Applicant has changed the dependency of claim 5 to overcome the objection under 37 CFR 1.75(c).

Withdrawal of these objections is respectfully requested.

Paragraphs 3-6: Claim Rejections - 35 USC § 103

The Examiner has rejected claims 1-4, 7-13 and 15-23 of the application as filed as being obvious from USP 6,284,193 to Carman in view of USP 4,770,851 to Joslyn. Applicant respectfully submits that the currently amended claims 1 and 12 define subject matter patentably distinguished from the teachings of Carman et al. and Joslyn, whether taken alone or in combination.

Applicant traverses Examiner's rejections.

From a study of its figures and description, it is apparent that the Carman et al. reference teaches a method and apparatus for using a continuous stream of ozone containing gas to reduce the biological load on consumer products or medical equipment. In contrast, the process of the present invention is a batch process, wherein sterilization gas is injected into the chamber and maintained in the chamber for a selected residence time. Carman et al. state that the use of Ozone in a static fashion

does not provide adequate sterilization. However, as mentioned, the method of the present application does employ Ozone in a static fashion. Carman et al. clearly state that prior art sterilization methods relying on filling the sterilization chamber with Ozone gas and exposing the materials therein to the sterilization gas without replenishing the sterilization gas are known, but not effective. Thus, Carman et al. clearly teach away from using a batch type sterilization process as disclosed and claimed in the present application. Moreover, the present invention addresses a specific problem associated mainly with batch type ozone sterilization processes carried out at high levels of relative humidity. Consequently, it is respectfully submitted that a person skilled in the art, when grappling with a batch process specific problem, would not turn to a prior art continuous process, such as the Carman et al. method, in trying to solve that problem, especially not when Carman et al. teach away from the use of a batch process.

In batch type processes run at high relative humidity, localized differentials in the temperature of the materials and the temperature in the sterilization chamber lead to localized condensation as the sterilization chamber atmosphere is humidified, and especially as it approaches saturation. This condensation, however, prevents access of the sterilant, the ozone gas, to the surface of the article to be sterilized, possibly leading to unsuccessful sterilization at the location of the condensation. Furthermore, this condensation often occurs at hard to reach locations, such as in interstices of the article (for example, hinges or pivots) or in small, semi-enclosed spaces, and will often remain at those locations even through successive sterilization cycles. This problem is now overcome according to the method of the present invention by

adding, prior to the step of humidifying the atmosphere in the sterilization chamber, the step of equalizing the temperature of the materials in the chamber with the temperature of the surrounding atmosphere, in order to avoid those localized temperature differentials. It is respectfully submitted that neither Carman et al. nor Joslyn, whether taken alone or in combination teach this solution.

Applicant submits that the claims as amended define a batch sterilization method and apparatus using ozone as the sterilization gas and employing a temperature equalization step. In this step, the temperature of any materials in the sterilization chamber is equalized with the temperature of the surrounding atmosphere in the sterilization chamber to avoid localized temperature differentials.

Currently amended claim 1 defines this step as follows:

prior to step (d), the temperature of the article is equalized with the temperature of an atmosphere in the sterilization chamber to prevent condensation of water on the article due to localized temperature differentials as the relative humidity in the sterilization approaches saturation.

Step (d) is the first step in the humidification of the sterilization chamber atmosphere. In step (d), a vacuum is applied to the sterilization chamber which is sufficient to lower the boiling point of water to below the ambient temperature in the chamber, so that any water supplied to the chamber in subsequent step (e) will evaporate and remain in the vapour phase. This is distinct from the methods of the references cited by the Examiner, neither of which teach such a temperature equalization step prior to humidification of the

sterilization chamber atmosphere. The Examiner states that Carman et al. do not teach such a temperature equalization step. The Examiner further states that the Joslyn process will necessarily lead to a temperature equalization. Although that may be the case, the manner in which this temperature equalization is achieved exaggerates the problem addressed by the present invention rather than overcoming it. Joslyn teaches a process for the removal of trapped, non-condensable gases prior to sterilization, by using a condensable gas to drive out the non-condensing gas. The condensable gas particularly disclosed is water vapour. Condensation of the condensing gas on the materials to be sterilized, and especially in the interstices of the materials, is desired in the Joslyn process. Thus, the Joslyn process, although possibly resulting in a temperature equalization, necessarily also results in condensation of water in the hard to reach interstices of the materials to be sterilized. This means the goal of the Joslyn process is the exact opposite of the process of the present invention. In the process of the invention, condensation of water in the interstices of an article to be sterilized is to be prevented, while it is desired in the Joslyn process. Thus, if the processes of Carman et al. and Joslyn were to be combined, the resulting method would not overcome the problem addressed by the present invention. It is furthermore respectfully submitted that a person skilled in the art grappling with the problem of localized sterilization failure due to condensation would not turn to the Joslyn process for a solution, since it is the goal of the Joslyn process to create condensation on the article to be sterilized. Moreover, although the Joslyn process may lead to a temperature equalization of the materials with the atmosphere in the chamber, the trapped condensation in the interstices

would either remain or, if evaporated, would lead to temperature differentials on the article as soon as a vacuum is applied to the sterilization chamber, as is necessary in the subsequent humidification and sterilization steps of the batch sterilization process. Consequently, as pointed out above, combining the Joslyn process with the Carman et al. process to achieve temperature equalization would not result in a process as defined in the currently amended claims, and would aggravate rather than overcome the problem addressed by the present invention.

Applicant respectfully requests the Examiner to withdraw his rejection of the claims under 35 USC 103(a).

Apparatus Claim 12

The Applicant respectfully submits that the same arguments also apply with respect to currently amended apparatus claim 12, which now clearly defines the purpose of the means for equalizing the temperature as being the prevention of condensation of water on the article due to localized temperature differentials. This is clearly opposite to the teachings of Joslyn and, thus, distinguished from a combination of Carman et al. and Joslyn.

Withdrawal of the rejection is respectfully requested.

Paragraph 7

The Examiner has rejected claim 14 under 35 USC 103(a) as unpatentable over Carman et al. in view of Joslyn and further in view of Faddis et al. Claim 14 is directed to a an apparatus as defined in claim 12, including a water reservoir (*inter alia*).

Applicant traverses the rejection.

In view of the amendment to claim 12, which renders that claim patentable over the combination of Carman et al. and Joslyn, the applicant believes the arguments presented above in relation to Carman et al. and Joslyn also apply to claim 14. Furthermore, since amended claim 14 includes all the features of amended claim 12 as well as the additional limitations of a door for sealing the sterilization chamber, a water reservoir, and a means for controlling the temperature of the chamber, the door, the humidifier and the water reservoir, claim 14 is submitted to be more limited in scope than amended claim 12. Therefore, in view of the arguments presented above, Applicant submits that claim 14 is patentable over Carman et al. in view of Joslyn and Faddis et al. Thus, Applicant respectfully submits that the apparatus of claim 14 is not rendered obvious by the teachings of Carman et al., Joslyn and Faddis et al. when taken alone or in combination.

Applicant respectfully requests withdrawal of the rejection of claim 14 under 35 USC 103(a).

Other Prior Art

With respect to the prior art made of record, but not relied on, Applicant respectfully submits that those references, whether taken alone or in combination would also not teach nor render obvious the method and apparatus of the claims as currently amended.

New Claims

New claims have been added and there are presently 2 independent claims and 25 claims in total pending in the application. Thus, 2 dependent claims were added.

U.S. Application No. 10/005,786
AMENDMENT A


Attorney Docket No.: 3648.028

Review and reconsideration of the Office Action of February 18, 2005, is respectfully requested in view of the above amendments and the following remarks.

Applicants have correctly amended the claims to overcome the claim objections cited by the Examiner.

All claims are now in condition for allowance. Favorable consideration and early issuance of the Notice of Allowance are respectfully requested. Should further issues remain prior to allowance, the Examiner is respectfully requested to contact the undersigned at the indicated telephone number.

Respectfully submitted,


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CERTIFICATE OF MAILING AND AUTHORIZATION TO CHARGE

I hereby certify that the foregoing AMENDMENT A for U.S. Application No. 10/005,786 filed November 8, 2001, was deposited in first class U.S. mail, with sufficient postage, addressed: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on May 18, 2005.

The Commissioner is hereby authorized to charge any additional fees, which may be required at any time during the prosecution of this application without specific authorization, or credit any overpayment, to Deposit Account No. 16-0877.


Yaté K. Cutliff